510(k) Summary

APPLICANT
Porous Media Corporation
1350 Hammond Road
St. Paul, MN 55110
Telephone: 651-653-2000
Fax: 651-653-2230
Contact: Keith Roberts
Title: Technical Business Development

DATE
6/20/06

NAME
HUMIDIFLOW™ Humidifier

CLASSIFICATION
Respiratory gas humidifier, 21 CFR 868.5450, Class II

PRODUCT CODE
BTT

DEVICE DESCRIPTION
The HUMIDIFLOW™ is a new device that humidifies oxygen. The device attaches to the inlet side of the air compressor and to the outlet oxygen used in oxygen concentrators and operates as a mass exchanger to transfer the room air humidity to the patient gas.

PREDICATE DEVICE
The Porous Media HUMIDIFLOW™ is substantially equivalent to the Allegiance bubble humidifier (subject of premarket notification K991484) and Salter Labs' bubbler (part number REF 7600) which has been on the market prior to 1976.

PERFORMANCE TESTING
Performance characteristics that could be affected by the installation of the HUMIDIFLOW™ were identified for the various oxygen concentrators for which HUMIDIFLOW™ would be installed. The device was also measured for humidity output. All testing indicates that the device is substantially equivalent to the predicate device.

INTENDED USE
Humidifiers are defined as a device that is intended to add moisture to the breathing gases for administration to a patient. The HUMIDIFLOW™ is intended to be installed on oxygen concentrators to add moisture to the breathing gases for administration to a patient.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

	HUMIDIFLOW™	Predicate Device (Salter Labs REF 7600)
Intended Use	For gas humidification	For gas humidification
Method of operation	Transfer of moisture vapor from atmospheric air to dry oxygen stream via diffusion	Transfer of moisture vapor and droplets to dry gas stream via bubble-through operation
Materials of construction	ProprietaryShell/End Caps: Nylon O-ring: Buna-N Tubing: USP Class VI, flexible vinyl Fittings: Nylon Membrane: [redacted]	N/A
Method of installation	Installs on the inlet side of the air compressor and oxygen outlet	Installs on the outlet oxygen stream

CONCLUSIONS DRAWN FROM NON-CLINICAL TESTING

The conclusions that can be drawn from the non-clinical testing are that the HUMIDIFLOW™ humidifier performs substantially equivalent as the predicate bubbler humidifier. The HUMIDIFLOW™ is biocompatible and manufactured with the identical membrane and adhesive components that are already used in other products we supply for gas flow path applications for the Puritan Bennett 840 ventilator subject of premarket notification K053388. The Polyester shell and endcaps used in the construction of the HUMIDIFLOW™ is identical to the Polyester shell used for a filter capsule provided to Respironics for the Millenium concentrator which was the subject of premarket notification K043006. Porous Media has also performed additional biocompatibility testing to show the HUMIDIFLOW™ is biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2006

Porous Media Corporation
C/O Mr. Neil E. Devine
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road Unit B7
Twinsburg, Ohio 44087

Re: K062091
Trade/Device Name: Humidflow ™
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: July 21, 2006
Received: July 24, 2006

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of August 8, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

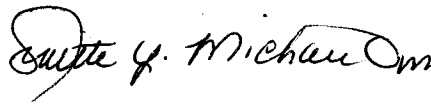
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A K062091

Device Name: Humidflow TM

Indications For Use: Humidifiers are defined as a device that is intended to add moisture to the breathing gases for administration to a patient.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K062091